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10/28/99

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PATENT APPLICATION SERIAL NO. 60-161085

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE
FEE RECORD SHEET

10/29/1999 MSHIFERA 00000080 60161085
01 FC:214 75.00 OP

PTO-1556
(5/87)
*U.S. GPO: 1998-433-214/80404

SERIAL NUMBER	FILING DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
60/161,085 PROVISIONAL	10/25/99		0000	

APPLICANT

GREGORY HERBERT LAMBRECHT, NATICK, MA.

CONTINUING DOMESTIC DATA********
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371 (NAT'L STAGE) DATA********
VERIFIED

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FOREIGN APPLICATIONS********
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Foreign Priority claimed 35 USC 119 (a-d) conditions met / Verified and Acknowledged	STATE OR COUNTRY	SHEETS DRAWING	TOTAL CLAIMS	INDEPENDENT CLAIMS
☐yes ☐no ☐yes ☐no ☐Met after Allowance Examiner's Initials _____ Initials	MA	5		

ADDRESS

GREG LAMBRECHT
220 ELIOT STREET
NATICK MA 01760

TITLE

METHODS AND DEVICES FOR INTERVERTEBRAL DISC REPAIR

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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53 (c).

INVENTOR(S)		
Given Name (first and middle (if any))	Family Name or Surname	Residence (City and either State or Foreign Country)
Gregory Herbert	Lambrecht	Natick, MA

☐ Additional inventors are being named on the ___ separately numbered sheets attached hereto

TITLE OF THE INVENTION (280 characters max)

Methods and Devices For Intervertebral Disc Repair

Direct all correspondence to: CORRESPONDENCE ADDRESS

☐ Customer Number → Type Customer Number here

OR

Place Customer Number Bar Code Label here

☒ Firm or Individual Name	Grecy Lambrecht				
Address	220 Eliot Street				
Address					
City	Natick	State	MA	ZIP	01760
Country	~~USA~~ USA	Telephone	508-655-2739	Fax	508 655-2739

ENCLOSED APPLICATION PARTS (check all that apply)

☑ Specification Number of Pages 7 ☑ Small Entity Statement

☑ Drawing(s) Number of Sheets 5 ☐ Other (specify)

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☑ A check or money order is enclosed to cover the filing fees — FILING FEE AMOUNT ($)

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The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

☑ No.

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Respectfully submitted,

SIGNATURE [signature] Date 10/22/99

TYPED or PRINTED NAME Grecy Lambrecht

TELEPHONE (508) 655-2739

REGISTRATION NO. (if appropriate)

Docket Number:

USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

This collection of information is required by 37 CFR 1.51. The information is used by the public to file (and by the PTO to process) a provisional application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 8 hours to complete, including gathering, preparing, and submitting the complete provisional application to the PTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C., 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Box Provisional Application, Assistant Commissioner for Patents, Washington, D.C., 20231.

Title

Methods And Devices For Intervertebral Disc Repair

Inventor

Greg Lambrecht

Background

The present invention relates to the surgical treatment of intervertebral (IV) discs in the lumbar, cervical, or thoracic spine that have suffered from herniation or significant disc height loss.

Herniation of an IV disc is one of the ten most common diagnoses in the United States. The disc performs the important role of absorbing mechanical loads while allowing for constrained flexibility of the spine. The disc is composed of a soft, central nucleus pulposus (NP) surrounded by a tough, woven anulus fibrosus (AF). Herniation is a result of a weakening in the AF. Symptomatic herniations occur when weakness in the AF allows the NP to bulge or leak posteriorly toward the spinal cord and major nerve roots. The most common resulting symptoms are pain radiating along a compressed nerve and low back pain, both of which can be crippling for the patient. The significance of this problem is increased by the low average age of diagnosis, with over 80% of patients in the U.S. being under 59.

Prior Art

Since its original description by Mixter & Barr in 1934, discectomy has been the most common surgical procedure for treating IV disc herniation. This procedure involves removal of disc materials impinging on the nerve roots or spinal cord posterior to the disc. Depending on the surgeon's preference, varying amounts of NP is then removed from within the disc space either through the herniation site or through a surgical incision in the AF. This removal of extra NP is commonly done to minimize the risk of recurrent herniation.

Nevertheless, the most significant drawbacks of discectomy are recurrence of herniation, recurrence of radicular symptoms, and increasing low back pain. Re-herniation can occur in up to 21% of cases. The site for re-herniation is most commonly the same level and side as the previous herniation and can occur through the same weakened site in the AF. Persistence or recurrence of radicular symptoms happens in many patients and when not related to re-herniation, tends to be linked to stenosis of the neural foramina caused by a loss in height of the operated disc. Debilitating low back pain occurs in roughly 14% of patients. All of these failings are most directly related to the loss of NP material and AF competence that results from herniation and surgery.

Loss of NP material deflates the disc, causing a decrease in disc height. Significant decreases in disc height have been noted in up to 98% of operated patients. Loss of disc

height increases loading on the facet joints. This can result in deterioration of facet cartilage and ultimately osteoarthritis and pain in this joint. As the joint space decreases the neural foramina formed by the inferior and superior vertebral pedicles also close down. This leads to canal stenosis, pinching of the traversing nerve root, and recurring radicular pain. Loss of NP also increases loading on the remaining AF, an innervated structure that can produce pain. Finally, loss of NP results in greater bulging of the AF under load. This can result in renewed impingement by the AF on nerve structures posterior to the disc.

Persisting tears in the AF that result either from herniation or surgical incision also contribute to poor results from discectomy. The AF has been shown to have limited healing capacity with the greatest healing occurring in its outer borders. Healing takes the form of a thin fibrous film that does not approach the strength of the uninjured disc. Surgical incision in the AF has been shown to produce immediate and long lasting decreases in stiffness of the AF particularly against torsional loads. This may over-stress the facets and contribute to their deterioration. Further, in as many as 30% of cases, the AF never closes. In these cases, not only is re-herniation a risk but also leakage of fluids from within the NP into the epidural space can occur. This has been shown to cause localized pain, irritation of spinal nerve roots, decreases in nerve conduction velocity, and may contribute to the formation of post-surgical scar tissue in the epidural space.

Other orthopedic procedures involving removal of soft tissue from a joint to relieve pain have resulted in significant, long lasting consequences. Removal of all or part of the menisci of the knee is one example. Partial and total meniscectomy leads to increased osteoarthritic degeneration in the knee and the need for further surgery in many patients. A major effort among surgeons to repair rather than resect torn menisci has resulted in more durable results and lessened joint deterioration.

To date, there have been very few attempts to repair the IV disc. Yasargil mentions suturing the AF closed after complete removal of the NP, but does nothing to limit disc height loss or posterior bulging of the AF.

Most of the relevant prior art pertains to repair of the menisci of the knee. Feagin, et. al. in US 5,500,000 discloses a system and method for repairing tears in soft tissues. The system is limited to a barbed tissue anchor, an attached length of suture, and a suture-retaining member, which can be affixed to the suture and used to draw the sides of a tear into apposition. The drawback of this method is that it is limited to the repair of a tear in soft tissue. In the IV disc, closure of a tear in the AF does not necessarily prevent further bulging of that disc segment toward the posterior neural elements. Further, there is often no apparent tear in the AF when herniation occurs. Herniation can be a result of a general weakening in the structure of the AF (soft disc) that allows it to bulge posteriorly without a rupture. When tears do occur, they are often radial. Placing an anchor across such a tear plane as disclosed in US 5,500,000 would require medial-lateral placement of the anchor. The limited exposure provided by the posterior elements of the vertebra and the orientation of the tissue planes and fibers of the AF make this invention very difficult to implant in the disc and of questionable therapeutic benefit. It is the primary purpose of

the present invention to prevent movement of the AF and any herniated material toward the posterior neural structures by suspending the herniated segment from a site within the FSU. Repairing a tear in the AF can accompany this method, but is not necessary for achieving the purpose of the disclosed invention. Feagin, et al. further does not disclose any augmentation of the injured soft tissue.

Oberlander in US 5,702,462 has all of the limitations of Feagin, et al. The disclosed invention is intended for repair of a tear in a previously contiguous soft tissue. Dart anchors are placed across the tear in a direction generally perpendicular to the plane of the tear. Sutures leading from each of at least two anchors are then tied together such that the opposing sides of the tear are brought together.

Shah in two related patents, US 5,556,428 and 5,769,893, discloses an apparatus and method of using tension to induce growth of soft tissue. The disclosed embodiments and methods are limited in their application to hernias of the IV disc in that they require a spring to apply tension. Aside from the difficulty of placing a spring within the limited space of the FSU, a spring will induce a continuous displacement of the attached tissues that could be deleterious to the structure and function of the disc. A spring may further allow a posterior bulge in the disc to progress should forces within the disc exceed the tension force applied by the spring. Further, the disclosed invention is designed to be removed once the desired tissue growth has been achieved. This has the drawback of requiring a second procedure.

There are numerous ways of augmenting the IV disc disclosed in the art. In reviewing the art, two general approaches are apparent – implants that are fixed to surrounding tissues and those that are not fixed, relying in stead on the AF to keep them in place.

The first type generally replace the entire disk, such as Stubstad in US 3,867,728, Frey in US 4,932,969, and Stone in U.S. 5,108,438. These concepts are limited in many ways. First, by replacing the entire disc they generally must endure all of the loads that are transferred through that disc space. Many degenerated discs are subject to pathologic loads that exceed those in normal discs. Hence, the designs must be extremely robust and yet flexible. None of these devices has yet been able to achieve both qualities. Further, devices that replace the entire disc must be implanted using relatively invasive procedures, normally from an anterior approach. They may also require the removal of considerable amounts of healthy disc material including the anterior AF. Further, the disclosed inventions must account for the contour of the neighboring vertebral bodies to which they are attached. Because each patient and each vertebra is different, these types of implants must be available in many sizes.

The second type of augmentation involves an implant that is not directly fixed to surrounding tissues. Examples include Ray's US 5,824,093, Felt's US 5,888,220, Krapiva's US 5,645,597, Bao's patents US 5,047,055 and US 5,192,326 and Baumgertner's series of patents US 5,702,454, US 5,171280, EP 0621020A1, and EP 0453393A1. These inventions rely on an AF that is primarily intact to hold them in place. The disclosed implants are generally inserted through a hole in the AF and either

expand, are inflated, or deploy expanding elements so as to be larger than hole through which they are inserted. The limitation of these concepts is that the AF is often not intact in cases requiring augmentation of the disc. There are either rents in the AF or structural weaknesses that would allow herniation or migration of the disclosed implants. In the case of a disc herniation, there are definite weaknesses in the AF that allowed the herniation to occur. Augmenting the NP with any of the above disclosed inventions without supporting the AF or implant risks re-herniation of the augmenting materials. Further, those inventions with deployable elements such as Ray's US 5,824,093 and Baumgarner's US 5,702,454 risk injuring the vertebral endplates or the AF indiscriminately. Many of the patents describe closing the AF at the site of insertion. This may help, but again herniations do not require a rent in the AF. Structural weakness in or delamination of the multiple layers of the AF can allow these implants to bulge toward the posterior neural elements. Additionally, as the disc continues to degenerate, rents in the posterior anulus may occur in regions other than the original operated site. A further limitation of these concepts is that they require the removal of much or all of the NP to allow insertion of the implant. This requires time and skill to achieve and may permanently alter the physiology of the disc.

It is the object of the disclosed invention to overcome the many limitations of the described prior art. It is a further object of this invention to reduce the long-term negative consequences of herniated discs by repairing and/or augmenting rather than resecting the soft tissues of the disc. It is a further object of this invention to prevent or reduce the occurrence of re-herniation and disc height loss following surgical therapy for herniated IV discs. It is a further object of this invention to increase the AF's resistance to posterior bulging and leakage of NP material while increasing its stiffness under load. It is a further object of this invention to permit the augmentation of the soft tissues of the disc in such a way so as to limit the risk of the herniation of any augmentation materials toward nerve structures posterior to the disc.

Summary Of The Invention

The present invention relates to devices and methods for closing a defect in the anulus fibrosis.

One method involves the insertion of a barrier means into the disc. This procedure can accompany surgical discectomy. It can also be done without the removal of any portion of the disc and further in combination with the insertion of an augmentation material or device into the disc.

The method consists of inserting the barrier means into the interior of the disc and positioning it proximate to the interior aspect of the anular defect. The barrier material is preferably considerably larger in area than the size of the defect, such that at least some portion of said barrier means abuts healthier anulus fibrosis. The device acts to seal the anular defect, recreating the closed isobaric environment of a healthy disc nucleus. This closure can be achieved simply by an over-sizing of the implant relative to the defect. It can also be achieved by affixing the barrier means to tissues within the functional spinal unit. In a preferred aspect of the present invention, the barrier means is affixed to the

anulus surrounding the anular defect. This can be achieved with sutures, staples, glues or other suitable fixation means. The barrier means may also be larger in area than the defect and be affixed to a tissue or structure opposite the defect, i.e. anterior tissue in the case of a posterior defect.

The barrier means is preferably relatively flexible in nature. It may be constructed of a woven material such as Dacron or Nylon. It may further be an expanded material such as expanded polytetrafluroethelene (e-PTFE). The barrier means may also be a biologic material such as cross-linked collagen or cellulous.

The barrier means may be a single piece of material. It may further have an expandable means that allows it to be expanded from a compressed state after insertion into the interior of the disc. This expandable means may be an active means such as a balloon, or passive, such as a hydrophilic material. The expandable means could further be a self expanding mesh of elastically deforming material.

The barrier means may be anchored to the disc in multiple locations. In one preferred embodiment, the barrier means can be affixed to the anular tissue in or surrounding the defect and further affixed to a secondary fixation site opposite the defect, i.e. the anterior anulus in a posterior herniation or the inferior or superior vertebral body. Tension can be applied between the primary and secondary fixation sites so as to move the anular defect toward the secondary fixation site. This may be particularly beneficial in closing defects that result in posterior herniations. By using this technique, the herniation can be moved and supported away from any posterior neural structures while further closing any defect in the anulus.

The barrier means may further be integral to a fixation means such that the barrier means affixes itself to tissues within the functional spinal unit.

Any of the methods described above can be augmented by the use of a second barrier means placed proximate to the outer aspect of said defect. The second barrier can further be affixed to the inner barrier means by the use of a fixation means such as suture.

Claims

A method of closing a defect in the anulus of an intervertebral disc, said IV disc being part of a functional spinal unit, involving the steps of

a) inserting a barrier means through an opening into the interior of said disc
b) positioning said barrier proximate to said defect
c) affixing said barrier to a portion of said functional spinal unit using a fixation means

A method of closing a defect in the anulus fibrosis of an intervertebral disc of a functional spinal unit involving the steps of,

a) inserting at least a portion of a barrier means through an opening into the interior of said disc

b) positioning said barrier proximate to said defect
c) affixing said barrier to a portion of said functional spinal unit using a fixation means

A method of closing a defect in the anulus fibrosis of an intervertebral disc, said IV disc being part of a functional spinal unit, involving the steps of:
a) inserting a barrier means into the interior of said disc through an opening that at least in part traverses said defect
b) affixing said barrier to a portion of said functional spinal unit using a fixation means

A method of closing a defect in the anulus fibrosis of an intervertebral disc, said IV disc being part of a functional spinal unit, involving the steps of:
a) inserting a barrier means into the interior of said disc
b) positioning said barrier proximate to said defect
c) affixing said barrier to a portion of said functional spinal unit using a fixation means

A method of closing a defect in the anulus fibrosis of an intervertebral disc, said IV disc being part of a functional spinal unit, involving the steps of:
a) inserting an expandable barrier means into the interior of said disc
b) positioning said barrier means proximate to said defect
c) expanding said barrier means

A method of closing a defect in the anulus fibrosis of an intervertebral disc, said IV disc being part of a functional spinal unit, involving the steps of:
d) inserting an expandable barrier means into the interior of said disc
e) positioning said barrier means proximate to said defect
f) expanding said barrier means and securing it to a portion of said functional spinal unit using a fixation means

A soft tissue repair device comprising:
a) an anchor means to provide secure attachment to a first soft tissue
b) a flexible attachment site adapted to receive sutures so as to affix said attachment site to a second soft tissue, said attachment site being flexibly affixed to said anchor means

A soft tissue repair device comprising:
a) an anchor means adapted to provide secure attachment to a first soft tissue
b) a flexible attachment site comprised of a woven or expanded material, said attachment site adapted to receive sutures so as to affix said attachment site to a second soft tissue, said attachment site being flexibly affixed to said anchor means

A method of closing a defect in the anulus fibrosis of an intervertebral disc of a functional spinal unit, involving the steps of:

a) inserting a barrier means through an opening into the interior of said disc
b) positioning said barrier proximate to at least that portion of said defect that is on the interior of said disc
c) affixing said barrier to a portion of said functional spinal unit using at least one fixation means

A method of repairing an anular defect in an intervertebral disc consisting of the following steps:
a) creating a small opening in the anulus through to the nucleus
b) inserting a barrier material into the hole and securing said material against the inner wall of said anulus

A method of augmenting an intervertebral disc involving the steps of:
a) creating an opening into the interior of the disc through the anulus fibrosis
b) inserting an augmentation material into the disc through said opening
c) inserting a barrier material into the disc through said opening and positioning said barrier material proximate to the interior aspect of said opening

A method of repairing an anular defect in an intervertebral disc consisting of the following steps:
a) inserting a first barrier means into the interior of the disc and positioning said barrier means proximate to the interior aspect of said defect
b) positioning a second barrier means proximate to the exterior aspect of said defect
c) affixing said first barrier means to said second barrier means using a fixation means

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STATEMENT CLAIMING SMALL ENTITY STATUS (37 CFR 1.9(f) & 1.27(b))--INDEPENDENT INVENTOR	Docket Number (Optional)

Applicant, Patentee, or Identifier: Greg H. Lambrecht

Application or Patent No.:

Filed or Issued:

Title: Methods and Devices For Intervertebral Disc Repair

As a below named inventor, I hereby state that I qualify as an independent inventor as defined in 37 CFR 1.9(c) for purposes of paying reduced fees to the Patent and Trademark Office described in:

- ☐ the specification filed herewith with title as listed above.
- ☒ the application identified above.
- ☐ the patent identified above.

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Each person, concern, or organization to which I have assigned, granted, conveyed, or licensed or am under an obligation under contract or law to assign, grant, convey, or license any rights in the invention is listed below:

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NAME OF INVENTOR	NAME OF INVENTOR	NAME OF INVENTOR
Greg H. Lambrecht		
Signature of Inventor	Signature of Inventor	Signature of Inventor
10/22/99		
Date	Date	Date

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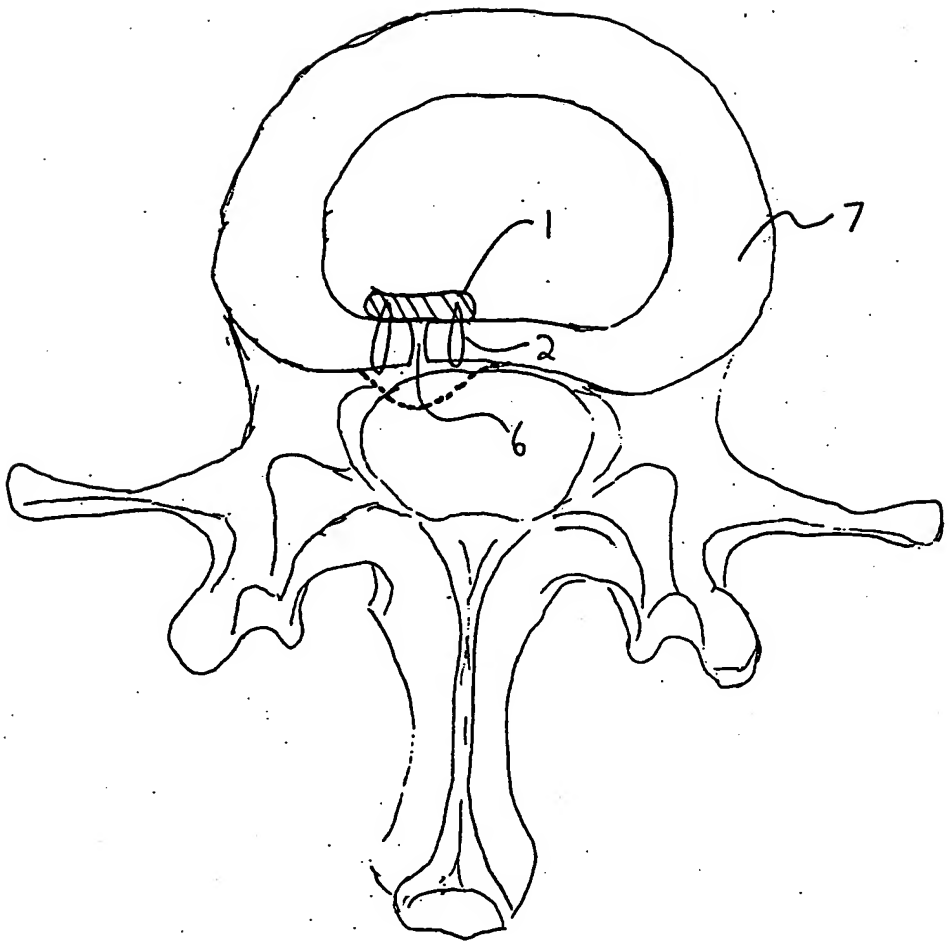


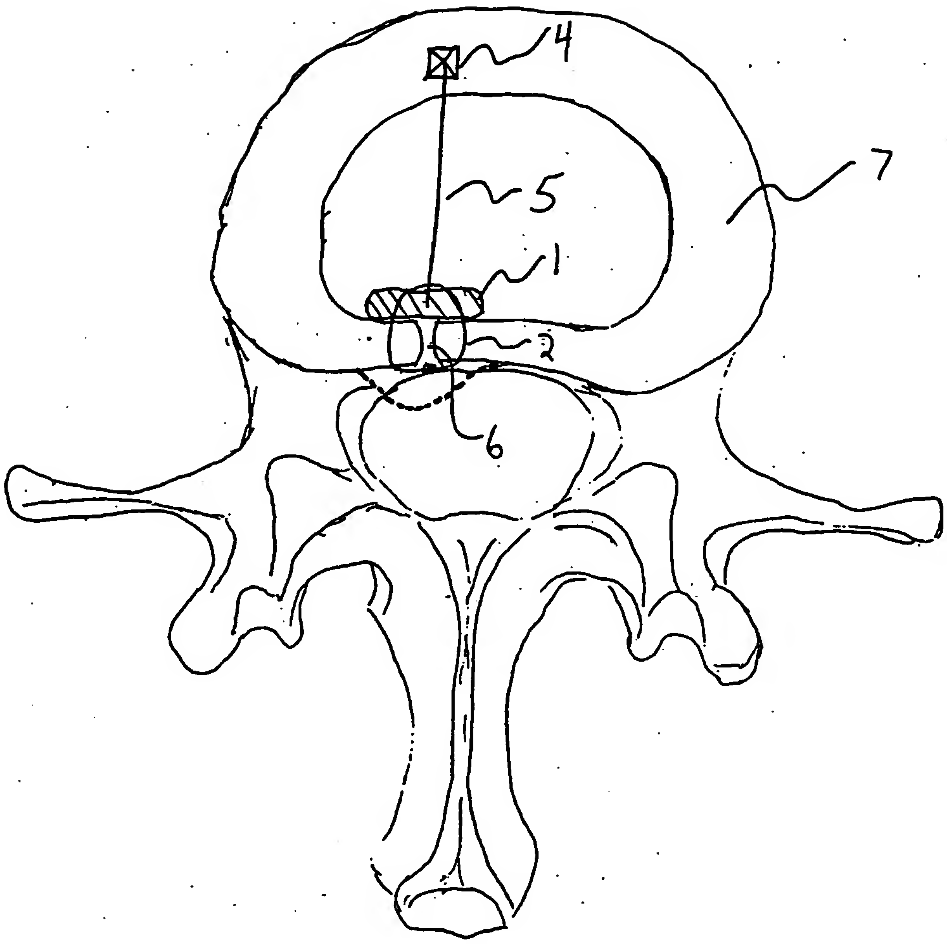
1: Barrier Material/Means

2: Fixation Means

6: Anular Defect

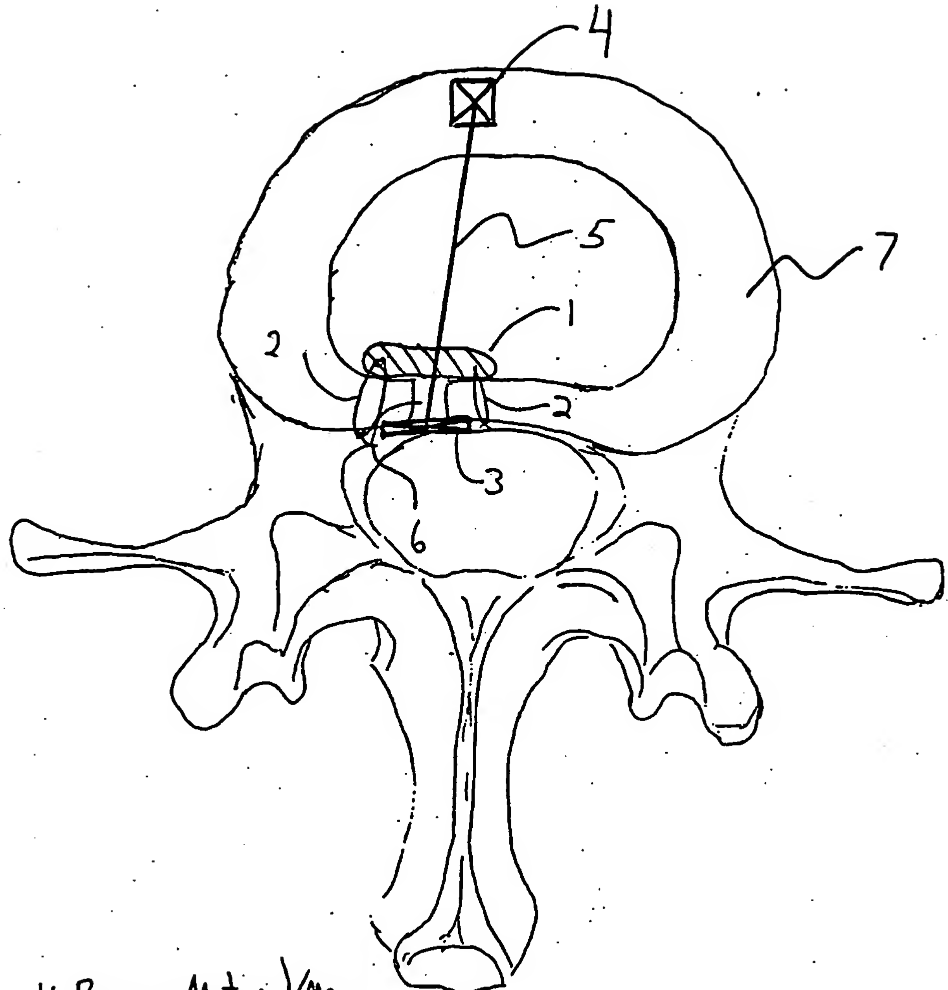
7: Anulus Fibrosis

Figure 1



1: Barrier Means
2: Fixation Means
4: Anchor Means
5: Connection Means
6: Anular Defect
7: Anulus Fibrosis

Figure 2



1: Barrier Material/Means

2: Fixation Means

3: External Barrier Material/means

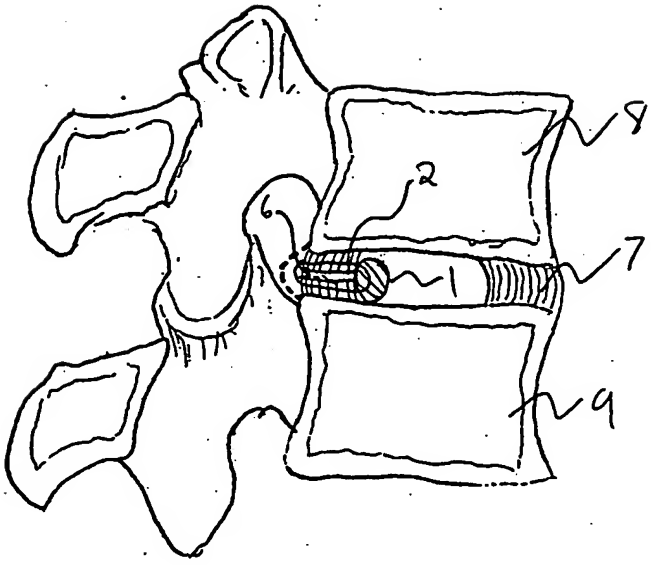
4: Anchor Means

5: Connection Means and Means To Fixate (3) to (1)

6: Anular Defect

7: Anulus Fibrosis

Figure 3



1: Barrier Means / Material

2: Fixation Means

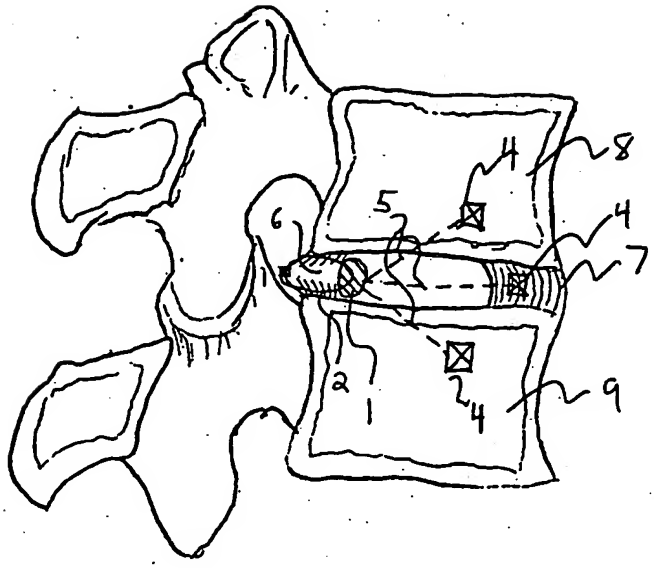
6: Anular Defect

7: Anulus Fibrosis

8: Superior Vertebral Body

9: Inferior Vertebral Body

Figure 4



1: Barrier Material / Means
2: Fixation Means
4: Anchor Means
5: Connection Means
6: Anular Defect
7: Anulus Fibrosis
8: Superior Vertebral Body
9: Inferior Vertebral Body

Figure 5

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12/18/00

PATENT APPLICATION
Attorney's Docket No 3005 1000-00U
VIA FACSIMILE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Gregory H. Lambrecht
U.S. Application No.:	60/149,490
Filed:	August 18, 1999
Title:	DEVICES AND METHODS OF VERTEBRAL DISC AUGMENTATION
Attorney Docket No.:	3005.1000-005

Applicants:	Gregory H. Lambrecht
U.S. Application No.:	60/161,085
Filed:	October 25, 1999
Title:	DEVICES AND METHODS OF VERTEBRAL DISC AUGMENTATION
Attorney Docket No.:	3005.1000-006

Applicants:	Gregory H. Lambrecht
U.S. Application No.:	60/172,996
Filed:	December 21, 1999
Title:	DEVICES AND METHODS OF VERTEBRAL DISC AUGMENTATION
Attorney Docket No.:	3005.1000-007

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60/149,490
60/161,085
60/172,996

Respectfully submitted,
HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

By _____
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Lexington, Massachusetts 02421-4799
Dated: December 18, 2000

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Application Number: 60/161,085	Filed: 10/25/99	
Group Art Unit:	Examiner:	

Paper No. #3

Assistant Commissioner for Patents
Washington, DC 20231

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1 (A) referred to in United States Patent Number 6,425,919, column Face.

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(12) **United States Patent**
Lambrecht

(10) **Patent No.: US 6,425,919 B1**
(45) **Date of Patent: Jul. 30, 2002**

(54) **DEVICES AND METHODS OF VERTEBRAL DISC AUGMENTATION**

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(73) Assignee: **Intrinsic Orthopedics, Inc.**, Wilmington, MA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 1 day.

(21) Appl. No.: **09/608,797**

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Related U.S. Application Data

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(51) Int. Cl.[7] A61F 2/44

(52) U.S. Cl. 623/17.16

(58) Field of Search 623/17.16; 128/898

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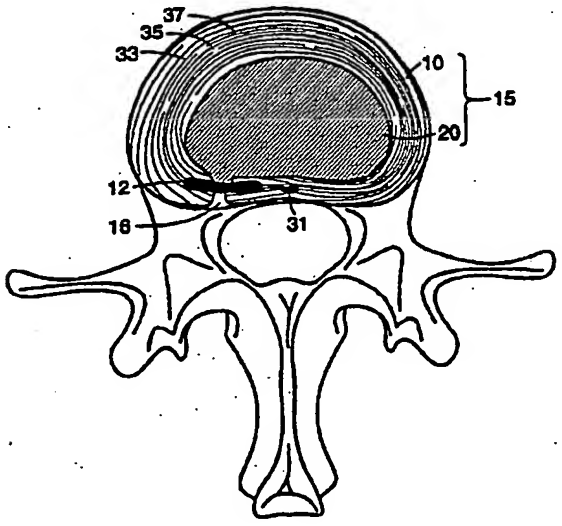
(57) **ABSTRACT**

A disk herniation constraining device for implantation into a vertebral disk can include a support member for support of a herniated portion of a disk. The support member can be connected to an anchor. The constraining device can include the insertion of augmentation material within the disk. A defect in the annulus of a disk can be closed using a prosthesis such as a barrier.

The barrier can be placed between the annulus and the nucleus of the disk. The barrier can include a sealant and an enlarger. The barrier can be implanted into the disk using a delivery cannule, an advancer and at least one control filament to control the positioning of the barrier over the defect. A stiffening element can be included within the barrier to impart stiffness to the barrier.

20 Claims, 64 Drawing Sheets



POSITION	INITIALS	ID NO.	DATE
FEE DETERMINATION			
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